ISRCTN15032219 https://doi.org/10.1186/ISRCTN15032219

Clinical study carried out to investigate the efficacy of two probiotic formulates on irritable bowel syndrome

Submission date
18/04/2016

Recruitment status
No longer recruiting

Registration date
19/04/2016

Overall study status
Completed

Last Edited
07/09/2016

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Irritable bowel syndrome (IBS) is a common, long-term disorder of the digestive system. It is part of a group of disorders called functional bowel disorders, as it affects the way the bowel (intestines) functions. IBS is associated with a number of digestive symptoms such as abdominal pain, diarrhoea, constipation and flatulence, which vary from person to person. The use of probiotics (live bacteria that are good for health as they replenish “good” bacteria that help the digestive system to work properly) has been shown to have beneficial effects on the health of people with IBS. The aim of this study is to compare two different probiotic mixtures in their effectiveness at treating irritable bowel syndrome with constipation (IBS-C).

Who can participate?
Adults with IBS-C.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group take capsules containing the first probiotic mix, which contains the bacteria Lactobacillus acidophilus and Lactobacillus reuteri, once a day for 60 days. Those in the second group group take capsules containing the first probiotic mix, which contains the bacteria Lactobacillus plantarum, Lactobacillus rhamnosus and Bifidobacterium animalis subspecies lactis, once a day for 60 days. Those in the third group take capsules containing a placebo (dummy) once a day for 60 days. All participants provide stool samples at the start of the study and then again after 10, 30, 60 and 90 days in order to measure the composition of the bacteria in the gut. At the same times, participants also complete a questionnaire about the IBS-C related symptoms they are having.

What are the possible benefits and risks of participating?
Participants who take the probiotic mixtures may benefit from an improvement to their IBS symptoms. There are no notable risks involved with taking part in this study.

Where is the study run from?
Farcoderm Clinic (Italy)

When is the study starting and how long is it expected to run for?
July 2013 to January 2015

Who is funding the study?
Ministry of Education, Universities and Research (Italy)

Who is the main contact?
Dr Anela Michelotti

Contact information

Type(s)
Scientific

Contact name
Dr Angela Michelotti

Contact details
Farcoderm S.R.L.
Via Mons. Angelini, 21
San Martino Siccomario
Italy
27028

Additional identifiers

Protocol serial number
MI.02.DS.L_2013/PROBIOPLUS 4 FOOD

Study information

Scientific Title
Effects of multispecies probiotic supplementation on irritable bowel syndrome: a randomized, double-blind, placebo-controlled trial

Study objectives
The aim of this study is to compare the clinical efficacy of two multispecies probiotic formulates, in particular their beneficial role in the functional bowel disorders will be state in comparison with a placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent Ethical Committee for Non-Pharmacological Clinical studies, 17/07/2013

Study design
Randomized double-blind three-arm placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Irritable bowel syndrome associated constipation (IBS-C)

Interventions
For the study 150 adult subjects, diagnosed with irritable bowel syndrome associated to constipation (IBS-C) were enrolled and divided in three groups (F_1, F_2, F_3). Each group received a daily oral administration of different probiotic mixtures (for a total period of 60 days). Participants are randomly allocated to one of three groups:

Group 1: Participants receive probiotics mix F_1 (Lactobacillus acidophilus and Lactobacillus reuteri) capsules to take once daily for 60 days.
Group 2: Participants receive probiotics mix F_2 (Lactobacillus plantarum, Lactobacillus rhamnosus and Bifidobacterium animalis subsp. lactis) capsules to take once daily for 60 days.
Group 3: Participants receive a placebo in the form of mix F_3 capsules to take once daily for 60 days.

Participants in all groups are followed for a further period of 30 days after a follow-up period from the last
ingestion of the tested products; during this period they doesn't take anything.

Intervention Type
Supplement

Primary outcome(s)
1. IBS-C symptoms are measured using the IBS-C questionnaire of related symptoms, which consists of five items (bloating, abdominal pain, constipation, abdominal cramps and flatulence) scored on a 10-point Visual Analogue Scale (VAS) at baseline, 10, 30 and 60 days
2. Gut colonization is determined through fecal microbiological analyses using species-specific qPCR on stool samples collected at baseline, 10, 30 and 60 days

Key secondary outcome(s))
Maintenance of the obtained effects are measured using IBS-C symptoms questionnaire microbiological analyses performed by species-specific qPCR 30 days after the last product(s) intake.

Completion date
30/01/2015

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years old
2. Suffering from Irritable Bowel Syndrome with constipation (IBS-C)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnancy or intention to become pregnant during the study period
2. Lactation
3. Food intolerances/allergy
4. Known history of gastro-intestinal disorders
5. Chronic or acute gastrointestinal disorders
6. Participation in another similar study
7. Unwillingness or inability to comply with the study protocol requirements
8. Currently using food supplements or drugs containing actives having an influence on gastro-intestinal physiology

Date of first enrolment
01/09/2013

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
Italy

Study participating centre
Farcoderm Clinic (Farcoderm Poliambulatorio)
Via Mons. Angelini, 21
San Martino Siccomario (PV)
Italy
27028

Sponsor information

Organisation
Farcoderm S.R.L.

Funder(s)

Funder type
Government

Funder Name
Ministero dell'Istruzione, dell'Università e della Ricerca

Alternative Name(s)
Ministry of Education, University and Research, Ministry of Education, Universities and Research, Italian Ministry for Universities and Research, Italian Ministry for Education, University and Research, Italian Ministry of Education, MIUR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes